DRAFT LEGISLATION ENTITLED THE "CLONING PROHIBITION ACT OF 1997"

MESSAGE

FROM

THE PRESIDENT OF THE UNITED STATES

TRANSMITTING

A DRAFT OF PROPOSED LEGISLATION TO PROHIBIT ANY ATTEMPT TO CREATE A HUMAN BEING USING SOMATIC CELL NUCLEAR TRANSFER, TO PROVIDE FOR FURTHER REVIEW OF THE ETHICAL AND SCIENTIFIC ISSUES ASSOCIATED WITH THE USE OF SOMATIC CELL NUCLEAR TRANSFER IN HUMAN BEINGS, AND FOR OTHER PURPOSES



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To the Congress of the United States:

I am pleased to transmit today for immediate consideration and prompt enactment the "Cloning Prohibition Act of 1997." This legislative proposal would prohibit any attempt to create a human being using somatic cell nuclear transfer technology, the method that was used to create Dolly the sheep. This proposal will also provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in human beings.

Following the February report that a sheep had been successfully cloned using a new technique, I requested my National Bioethics Advisory Commission to examine the ethical and legal implications of applying the same cloning technology to human beings. The Commission concluded that at this time "it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning" and recommended that Federal legislation be enacted to prohibit such activities. I agree with the Committee's conclusion and am transmitting this legislative proposal to implement its recommendation.

Various forms of cloning technology have been used for decades resulting in important biomedical and agricultural advances. Genes, cells, tissues, and even whole plants and animals have been cloned to develop new therapies for treating such disorders as cancer, diabetes, and cystic fibrosis. Cloning technology also holds promise for producing replacement skin, cartilage, or bone tissue for burn or accident victims, and nerve tissue to treat spinal cord injury. Therefore, nothing in the "Cloning Prohibition Act of 1997" restricts activities in other areas of biomedical and agricultural research that involve: (1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or (2) the use of somatic cell nuclear transfer techniques to create animals.

The Commission recommended that such legislation provide for further review of the state of somatic cell nuclear transfer technology and the ethical and social issues attendant to its potential use to create human beings. My legislative proposal would implement this recommendation and assign responsibility for the review, to be completed in the fifth year after passage of the legislation, to the National Bioethics Advisory Commission.

I urge the Congress to give this legislation prompt and favorable consideration.

WILLIAM J. CLINTON.

THE WHITE HOUSE, June 9, 1997.

A BILL

To prohibit any attempt to create a human being using somatic cell nuclear transfer, to provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in human beings, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.—This Act may be cited as the "Cloning Prohibition Act of 1997".

SECTION 2. FINDINGS.

- (a) It has been reported that an adult sheep has been cloned using a technique called somatic cell nuclear transfer, a form of cloning.
- (b) The National Bioethics Advisory Commission (NBAC) has reviewed the scientific and ethical implications of this technology's potential use to clone human beings.

(1) NBAC has found that:

(a) Somatic cell nuclear transfer technology may have many applications for biotechnology, livestock production, and new medical approaches including the production of pharmaceutical proteins and prospects for regeneration and repair of human tissues.

- (b) However, the possibility of using somatic cell nuclear transfer for the purposes of creating a child entails significant scientific uncertainty and medical risk. Potential risks, known and unknown, could result in harm to a child.
- (2) The NBAC concluded unanimously that at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning. The Commission's consensus is based on current scientific information indicating that this technique is not safe to use in humans at this point.
- (3) Moreover, in addition to issues of safety, the Commission identified many additional serious ethical concerns which they agreed require a great deal more widespread and careful public deliberation before this technology may be used.
- (4) NBAC recommended a continuation of the current moratorium on the use of Federal funds to support any attempt to create a child by somatic cell nuclear transfer, and an immediate request to all firms,

clinicians, investigators, and professional societies to comply voluntarily with the intent of the Federal moratorium.

- (5) NBAC further recommended that Federal legislation be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning.
- (6) NBAC also recommended that the United States cooperate with other countries to enforce mutually supported restrictions on this activity.
- (7) NBAC specified that the legislation should include a sunset provision and that, prior to the sunset date, an oversight body should review and report on the status of somatic cell nuclear transfer technology and the ethical and social issues associated with its use and recommend whether the prohibition should be continued.
- (8) The Commission concluded that any regulatory or legislative actions undertaken to effect the foregoing prohibition should be carefully written so as not to interfere with other important areas of research, such as the cloning of human DNA sequences and cells, which raise neither the scientific nor the ethical issues that arise from the possible creation of children through somatic

cell nuclear transfer techniques.

- (9) The Commission also found that cloning animals by somatic cell nuclear transfer does not raise the same issues implicated in attempting to use the technique to create a child, and its continuation should only be subject to existing regulations regarding the humane use of animals.
- (c) Biomedical research facilities, including those conducting cloning, and reproductive services facilities affect interstate commerce.

SECTION 3. PURPOSES. - The purposes of this Act are-

- (a) To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and
- (b) To provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in humans.

SECTION 4. DEFINITIONS.

- (a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human.
- (b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm).
- (c) "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the

nucleus has been removed.

- SECTION 5. PROHIBITION.—It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being.
- SECTION 6. PROTECTED BIOMEDICAL RESEARCH.—Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:
 - (1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or
 - (2) the use of somatic cell nuclear transfer techniques to create animals.

SECTION 7. PENALTIES .-

- (a) Any person who intentionally violates Section 5 shall be fined the greater of \$250,000 or two times the gross gain or loss from the offense.
- (b) If a person is violating or about to violate Section 5, the Attorney General may commence a civil action in Federal district court to enjoin such violation.
- (c) Any property, real or personal, derived from or used to commit a violation or attempted violation of Section 5, or

any property traceable to such property, is subject to forfeiture to the United States in accordance with the procedure set forth in Chapter 46 of Title 18 of the United States Code.

(d) The Attorney General of the United States shall have exclusive enforcement authority under this Act.

SECTION 8. EFFECTIVE DATE.-This Act shall apply to somatic cell nuclear transfers performed within five years after the date of its enactment.

later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on (1) the state of the science of somatic cell nuclear transfer; (2) the ethical and social issues associated with the potential use of this technology in humans; and (3) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 10. RIGHT OF ACTION.—Nothing in this Act shall be construed to give any individual or person a private right of action.